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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,371	01/16/2001	Michael F. Holick	1825.0100001/RWE	1891

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EXAMINER
FONDA, KATHLEEN KAHLER

ART UNIT	PAPER NUMBER
1623	9

DATE MAILED: 12/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/759,371	HOLICK ET AL.	
	Examiner	Art Unit	
	Kathleen Kahler Fonda, Ph.D.	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12-18-01 (IDS) and 3-21-02 (IDS)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6 & 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place it in proper dependent form, or rewrite the claim in independent form. Specifically, claim 1 requires a glycoside derivative of a glucocorticosteroid, and claim 8 recites compounds which are not glycosides.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by KARLSSON *et al.* (A). Paragraph 0016 of KARLSSON

teaches that a number of glucocorticosteroids may be formulated for nasal or oral administration to treat inflammation. As noted above, claim 8 does not properly depend from claim 1, so independent claim 1 is not included in this rejection.

Claims 1-3, 5, 6, and 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by BRATTSAND *et al*. (AH). BRATTSAND teaches glycoside derivatives of glucocorticosteroids as claimed, and their formulation as pharmaceutical compositions; see columns 3-5. Claims 13-16 merely provide limitations on the intended use of the composition, and thus cannot be bases for patentability. Thus the claims are anticipated.

Claims 1-8 and 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by MARX (U.S. Patent 3,733,318, reference AA1). MARX teaches glycoside derivatives of glucocorticosteroids as claimed, and their formulation as pharmaceutical compositions. See, for example, formula II in column 2 which is an orthoester, and column 15, lines 54-65. Thus the claims are anticipated.

Claims 1-3 and 5-16 are rejected under 35 U.S.C. 102(e) as being anticipated by FRIEND *et al.* (EP 0 123 485, reference AC1). See compounds 1, 2, 14, 15, and Example 1, which teach compounds of the claims and their formulation for administration to rats. Thus the claims are anticipated. Claim 8 is included in this rejection insofar as Applicant may have intended to claim glycoside derivatives of the named glucocorticosteroids. As for claims requiring compounds which do not "have a high first pass metabolism in the liver," the Examiner notes that FRIEND teaches the prednisone and prednisolone derivatives of claims 9 and 10, which inherently possess this property, according to the specification. Claims 13-16 merely provide limitations on the intended use of the composition, and thus cannot be bases for patentability. Thus the claims are anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject

matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over either MARX (U.S. Patent 3,733,318, reference AA1) or FRIEND *et al.* (EP 0 123 485, reference AC1), further in view of either KARLSSON *et al.* (A) or ANDERSSON *et al.* (B).

Applicant claims methods of treating or ameliorating inflammatory disease by topical, intranasal, or oral administration, or by inhalation, of a glycoside derivative of a glucocorticosteroid which does not have a high first pass metabolism in the liver.

Each of MARX and FRIEND teaches as set forth above. Neither MARX nor FRIEND specifically discloses administration by the routes according to claims 17-20 .

KARLSSON teaches that glucocorticosteroids may be formulated "for use in nasal and oral inhalation" for treatment of inflammatory disorders; see paragraph 0016.

ANDERSSON teaches that glucocorticosteroids may be administered directly to the respiratory tract or the skin, to treat disorders including inflammation; see column 1, lines 14-37.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to administer the glycoside derivatives of glucocorticosteroids taught by MARX or FRIEND according to the routes of KARLSSON or ANDERSSON. An ordinarily skilled worker would have been motivated to do so, with a reasonable expectation of success, because although the glucocorticosteroids of KARLSSON and ANDERSSON are not glycosides, they are taught to be useful for the same inflammatory indications as the glycoside derivatives of MARX and FRIEND. One skilled in the art could readily have formulated the glycoside derivatives of MARX or FRIEND to be administered nasally or orally based on the teaching of KARLSSON or ANDERSSON.

No claim is allowed.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see http://www.uspto.gov/ebc/index.html for more information. Also, http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be

directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

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Primary Examiner
Art Unit 1623